

Iovate Health Sciences U.S.A. Inc.  
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Blasdell, NY 14219

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June 8, 2005

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Office of Nutritional Products, Labeling, and Dietary Supplements (HFS-800)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

**NOTIFICATION OF STATEMENT OF NUTRITIONAL SUPPORT**

Dear Sir or Madam:

In accordance with Section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act, and pursuant to 21 C.F.R. § 101.93, we hereby provide the following notice with regard to the marketing of the Dietary Supplement described below:

Distributor: Iovate Health Sciences U.S.A. Inc., 3880 Jeffrey Blvd., Blasdell, NY 14219

Name of Supplement: **LeanBalance™**

Statement of Nutritional Support:

- **HEALTHY WEIGHT LOSS**
- LeanBalance™ is an advanced weight-loss formula designed for people looking for a healthy way to lose weight and maintain a healthy lifestyle. Calci-Triplex™ blend – our unique combination of three sources of calcium – enhances your body's own ability to burn fat.
- Two scientific studies show that dieting subjects who exercised and used the key ingredients in LeanBalance, lost, on average, 12 and 15 pounds in just 8 weeks - up to 3 times more than those who only dieted and exercised. LeanBalance helps you take it off, and get your daily dose of calcium too! LeanBalance. Healthy weight loss for a radiant you.

To the best of my knowledge, the information contained in this notice is complete and accurate, and Iovate Health Sciences USA Inc. has substantiation that the statements are truthful and not misleading.

Sincerely,

Shan Chaudhuri  
Regulatory Affairs Manager

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